VASCULAR PROSTHESIS INCLUDING TORSIONAL STABILIZER AND METHODS OF USE

Reference to Related Applications

[0001] This application is a continuation-in-part of United States Patent Application Serial No. 10/342,427, filed January 13, 2003, which claims priority from United States provisional patent application Serial No. 60/433,065, filed December 24, 2002.

Field Of The Invention

[0002] The present invention relates to an implantable vascular prosthesis configured for use in a wide range of applications, and more specifically, a ribbon-type prosthesis having a torsional stabilizer that increases frictional engagement with a vessel wall.

Background of the Invention

[0003] Today there are a wide range of intravascular prostheses on the market for use in the treatment of aneurysms, stenoses, and other vascular irregularities. Balloon expandable and self-expanding stents are well known for restoring patency in a stenosed vessel, e.g.,

after an angioplasty procedure, and the use of coils and stents are known techniques for treating aneurysms.

[0004] Previously-known self-expanding stents generally are retained in a contracted delivery configuration using an outer sheath, then self-expand when the sheath is retracted. Such stents commonly have several drawbacks, for example, the stents may experience large length changes during expansion (referred to as "foreshortening") and may shift within the vessel prior to engaging the vessel wall, resulting in improper placement. Additionally, many self-expanding stents have relatively large delivery profiles because the configuration of their struts limits further compression of the stent. Accordingly, such stents may not be suitable for use in smaller vessels, such as cerebral vessels and coronary arteries.

[0005] Other drawbacks associated with the use of coils or stents in the treatment of aneurysms is that the coils or stents, when deployed, may have a tendency to straighten or otherwise remodel a delicate cerebral vessel, which may cause further adverse consequences. Moreover, such devices may not adequately reduce blood flow from the cerebral vessel into the sac of the aneurysm, which may increase the likelihood of rupture. Generally, if a greater surface area is employed to cover the sac, the delivery profile of the device may be compromised due to the increased surface area, and the device also may be more rigid and cause remodeling of the vessel.

[0006] For example, PCT Publication WO 00/62711 to Rivelli describes a stent comprising a helical mesh coil having a plurality of turns and including a lattice having a multiplicity of pores. The lattice is tapered

along its length. In operation, the plurality of turns are wound into a reduced diameter helical shape, then constrained within a delivery sheath. The delivery sheath is retracted to expose the distal portion of the stent and anchor the distal end of the stent. As the delivery sheath is further retracted, the subsequent individual turns of the stent unwind to conform to the diameter of the vessel wall.

[0007] The stent described in the foregoing publication has several drawbacks. For example, due to friction between the turns and the sheath, the individual turns of the stent may bunch up, or overlap with one another, when the delivery sheath is retracted. In addition, once the sheath is fully retracted, the turns may shift within the vessel prior to engaging the vessel wall, resulting in improper placement of the stent. Moreover, because the distal portion of the stent may provide insufficient engagement with the vessel wall during subsequent retraction of the remainder of the sheath, ambiguity concerning accuracy of the stent placement may arise.

[0008] When utilizing stents in interventional procedures, it may be advantageous to deliver therapeutic agents to a vessel wall via the surface of the stent. Such drug eluting stents have many advantages, such as controlled delivery of therapeutic agents over an extended period of time without the need for intervention, and reduced rates of restenosis after angioplasty procedures. Typically, the drug is disposed in the matrix of a bioabsorbable polymer coated on an exterior surface of the struts of the stents, and then gradually released into a vessel wall. The quantity of the therapeutic agent provided by the stent generally is

limited by the surface area of the struts. Increasing the surface area of the struts may enhance drug delivery capability, but may compromise the overall delivery profile of the stent. There therefore exists a need for a prosthesis having a reduced delivery profile and enhanced drug delivery capabilities.

[0009] In view of these drawbacks of previously known devices, it would be desirable to provide apparatus and methods for an implantable vascular prosthesis comprising a ribbon-type stent having a torsional stabilizer, wherein the prosthesis is configured to be used in a wide range of applications including, but not limited to, treating aneurysms, maintaining patency in a vessel, and delivering drugs to a vessel.

[0010] It also would be desirable to provide apparatus and methods for a vascular prosthesis comprising a ribbon-type stent having a torsional stabilizer that enhances frictional engagement with the vessel.

[0011] It further would be desirable to provide apparatus and methods for a vascular prosthesis having a distal anchoring section that allows for controlled deployment of a ribbon-type stent at a desired location within a vessel.

[0012] It yet further would be desirable to provide apparatus and methods for a vascular prosthesis that has a substantially small delivery configuration to allow the prosthesis to be used in smaller vessels.

Summary Of The Invention

[0013] In view of the foregoing, it is an object of the present invention to provide apparatus and methods for an implantable vascular prosthesis comprising a ribbon-type stent having a torsional stabilizer, wherein

the prosthesis is configured to be used in a wide range of applications including, but not limited to, treating aneurysms, maintaining patency in a vessel, and delivering drugs to a vessel.

[0014] It is also an object of the present invention to provide apparatus and methods for a vascular prosthesis comprising a ribbon-type stent having a torsional stabilizer that provides frictional engagement with the vessel wall.

[0015] It is another object of the present invention to provide apparatus and methods for a vascular prosthesis having a distal anchoring section that allows for controlled deployment of the prosthesis at a desired location within a vessel.

[0016] It is a further object of the present invention to provide apparatus and methods for a vascular prosthesis that has a substantially small delivery configuration to allow the prosthesis to be used in smaller vessels.

[0017] These and other objects of the present invention are accomplished by providing a vascular prosthesis comprising a distal anchor section joined a helical mesh proximal section and including a torsional stabilizer, wherein the prosthesis is configured to engage a vessel wall and adapt to a natural curvature of the vessel wall. The torsional stabilizer is an extension of the proximal section and enhances contact and friction with the vessel wall. The vascular prosthesis may be used in a wide range of applications, such as treating aneurysms, maintaining patency in a vessel, e.g., after an angioplasty procedure, and other procedures requiring a controlled delivery of therapeutic drugs to a vessel.

[0018] In a preferred embodiment, the vascular prosthesis comprises a shape memory material, such as Nitinol, and includes a distal anchor section having a generally zig-zag or cell-like configuration coupled to a proximal helical section having a helical mesh configuration formed of a plurality of turns.

[0019] The prosthesis is delivered to a target vessel in a contracted state, constrained within an outer sheath, in which radially inwardly directed compressive forces are applied by the outer sheath to the distal section. In the contracted state, the helical proximal section and torsional stabilizer are wound down to a smaller configuration, so that adjacent turns preferably partially overlap, and are constrained in the contracted state by the outer sheath.

[0020] In a preferred method of operation, the distal section, proximal section and torsional stabilizer are provided in their respective contracted states within the outer sheath and the prosthesis is fluoroscopically advanced into a selected vessel using techniques that are per se known in the art. The proximal section then is positioned adjacent a target region of a vessel, such as an aneurysm or a stenosed region, with the distal section positioned distal of the target region. The outer sheath then is retracted proximally to cause the distal section to self-deploy and engage an inner wall of the vessel distal of the target region. A distal portion of the distal section may be biased radially outward, or provided with proximally-directed barbs, to facilitate secure anchoring of the distal section within the vessel.

[0021] Once the distal section is securely anchored distal of the target region, the outer sheath further is retracted to cause the proximal section to self-deploy

and engage the vessel wall at the target region. Advantageously, by providing a distal anchoring element prior to deploying the proximal section, each turn of the helical proximal section will unwind in a controlled manner as the outer sheath is retracted. This technique ensures that the prosthesis will not shift within the vessel during deployment.

[0022] The vascular prosthesis of the present invention is flexible enough to conform to the shape of a delicate vessel without substantially remodeling the vessel. In particular, the zig-zag or cell-like configuration of the distal section may conform to a natural curvature of a vessel wall better than traditional stents having interconnected struts, which may be more rigid. Additionally, the helical mesh configuration of the proximal section conforms to vasculature of the target region since each of the plurality of turns is free to assume a curved configuration substantially independently of one another. Also, because the proximal section of the vascular prosthesis has a ribbon-like structure, the proximal section may be wound down to a contracted state with a substantially reduced delivery profile, compared to slotted-tube stents. This feature makes the stent of the present invention especially useful for treating defects in smaller vessels, such as cerebral arteries.

[0023] In accordance with another aspect of the present invention, the plurality of turns may comprise a substantially increased surface area relative to conventional stents that have a plurality of interconnected struts. The increased surface area of the turns is particularly advantageous for localized drug delivery. The turns may be coated with a drug-laden

polymer coating or, alternatively, one or more dimples or through-holes may be disposed in a lateral surface of the turns to elute drugs over an extended period of time.

[0024] Methods of using the vascular prosthesis of the present invention, for example, in the treatment of an aneurysm, also are provided.

Brief Description Of The Drawings

[0025] Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

[0026] FIGS. 1A-1B are, respectively, side and perspective views of a vascular prosthesis of the present invention;

[0027] FIG. 2 is a side view describing features of the junction of the prosthesis of FIG. 1;

[0028] FIG. 3 is a side view of a vascular prosthesis having a distal section that is biased radially outward;

[0029] FIG. 4 is an enlarged view of the distal end of the prosthesis of FIG. 3;

[0030] FIG. 5 is a side view illustrating different drug delivery modalities;

[0031] FIG. 6 is a side sectional view of a delivery system that may be used in conjunction with the vascular prosthesis of FIG. 1;

[0032] FIGS. 7A-7C are side sectional views illustrating use of the vascular prosthesis of FIG. 1 in the treatment of an aneurysm;

[0033] FIGS. 8A-8B are, respectively, side and perspective views of an alternative embodiment of the vascular prosthesis of the present invention;

[0034] FIGS. 9A-9B are, respectively, side and perspective views of a vascular prosthesis including a torsional stabilizer according to the present invention;

[0035] FIG. 10 is a detailed side view of the torsional stabilizer portion of the vascular prosthesis of FIG. 9;

[0036] FIG. 11 is a side view of the torsional stabilizer portion of an alternative vascular prosthesis; and

[0037] FIG. 12 is a side view of the torsional stabilizer portion of another alternative vascular prosthesis.

Detailed Description Of The Invention

[0038] The present invention is directed to an implantable vascular prosthesis configured for use in a wide range of applications, such as treating aneurysms, maintaining patency in a vessel, and allowing for the controlled delivery of therapeutic agents to a vessel wall. The prosthesis has a ribbon-type configuration that provides a substantially smaller delivery profile than other known devices, while having an increased surface area to allow for delivery of the therapeutic agents. Additionally, the prosthesis is configured to conform to a vessel wall without substantially remodeling the vessel, and further is configured to provide improved accuracy during deployment relative to previously known devices.

[0039] Referring now to FIGS. 1, a first embodiment of a vascular prosthesis constructed in accordance with principles of the present invention is described. Vascular prosthesis 20 comprises proximal section 22 and distal section 24, each capable of assuming contracted

and deployed states. In FIGS. 1, proximal and distal sections 22 and 24 are each depicted in their respective deployed states.

[0040] Vascular prosthesis 20 preferably is formed from a solid tubular member comprising a shape memory material, such as nickel-titanium alloy (commonly known in the art as Nitinol). The solid tubular member then is laser cut, using techniques that are per se known in the art, to a desired deployed configuration, as depicted in FIG. 1A. An appropriate heat treatment, per se known in the art, then may be applied to solid regions 33 of vascular prosthesis 20 while the device is held in the desired deployed configuration. The treatment of the shape memory material allows vascular prosthesis 20 to self-deploy to the desired deployed configuration, depicted in FIGS. 1, for purposes described hereinafter.

[0041] Distal section 24 preferably has a generally zig-zag configuration in the deployed state, as shown in FIG. 1A. The zig-zag configuration preferably is formed by laser cutting a solid tube, as described hereinabove, to form a pattern comprising plurality of struts 31 disposed between plurality of bends 32.

[0042] Proximal section 22 preferably comprises a helical mesh configuration in the deployed state, as depicted in FIGS. 1. The helical mesh configuration includes a plurality of substantially flat turns 26. Plurality of turns 26 may include a multiplicity of openings provided in different shapes and sizes, as illustrated by larger rectangular openings 25, smaller rectangular openings 28 and small circular openings 29. The multiplicity of openings are disposed between solid regions 33 of the shape memory material used to form vascular prosthesis 20. Alternatively, turns 26 may

comprise fully covered sections 39, as depicted hereinbelow in FIG. 7C.

[0043] As will be apparent to one skilled in the art of stent design, the configuration of proximal section 22 depicted herein is merely for illustrative purposes. Any combination of covered sections 39, circular openings 29, large or small rectangular openings, or any other shape may be provided along portions of turns 26, as desired. Plurality of turns 26 similarly may comprise exclusively one type of opening, such as small circular openings 29. Alternatively, plurality of turns 26 may be completely solid, such that the openings are omitted altogether. As will be apparent to those skilled in the art, the combination of solid regions and openings may be selectively provided along the length of proximal section 22, for example, to selectively increase surface area and drug delivery capabilities along proximal section 22, or to influence flow dynamics within a vessel.

[0044] Proximal section 22 includes distal turn 34 that transitions into bend 32 of distal section 24, thereby forming junction 23. Proximal turn 35 of proximal section 22 forms a free end that permits proximal section 22 to conform to a natural configuration of a patient's vessel, as described hereinbelow with respect to FIGS. 7.

[0045] Referring now to FIG. 2, features of junction 23 of FIGS. 1 are described in greater detail. Junction 23 is disposed between proximal and distal sections 22 and 24 of vascular prosthesis 20. Junction 23 preferably comprises extension strut 47 that is coupled to at least one bend 32 of distal section 24. Junction 23 extends in a proximal direction towards proximal section 22 and

ultimately transitions into proximal wall 42 of distal turn 34, as shown in FIG. 2.

[0046] Junction 23 further preferably comprises substantially orthogonal segment 48, i.e., a segment that is substantially orthogonal to a longitudinal axis of vascular prosthesis 20. Segment 48 transitions into extension strut 47 in the vicinity of bend 32, and further transitions into distal wall 41 of distal turn 34, as shown in FIG. 2.

[0047] Junction 23 may comprise one or more radiopaque markers 44, such as a radiopaque marker band or coating. Radiopaque marker 44 facilitates positioning of junction 23 at a desired longitudinal position within a patient's vessel, and further facilitates alignment of vascular prosthesis 20 at a desired radial orientation within the vessel. For example, radiopaque marker 44 may be used to orient proximal section 22 so that a desired lateral surface of proximal section 22, e.g., comprising covered sections 39 or small circular openings 29, deploys to overlay the arc of a vessel in which an aneurysm is situated.

[0048] It will be apparent to those skilled in the art that junction 32 may comprise other strut arrangements to connect distal section 24 to proximal section 22. For example, more than one extension struts 47 may be coupled between bends 32 and distal turn 34 of proximal section 22. Alternatively, proximal and distal sections 22 and 24 may be manufactured as two distinct sections, then coupled together to form a junction. In this embodiment, the junction may be formed when distal turn 34 of proximal section 22 is coupled to one or more bends 32 situated at proximal end 37 of distal section 24. Distal turn 34 may be coupled to one or more bends 32 using a

means for bonding, such as a solder, or the sections alternatively may be mechanically coupled together, for example, using a rivet or any other means, as will be apparent to one skilled in the art.

[0049] Referring now to FIG. 3, an alternative embodiment of distal section 24 of FIGS. 1 is described. In FIG. 3, distal section 24′ has proximal end 37 and distal end 38. Distal end 38 is biased radially outward with respect to the longitudinal axis of vascular prosthesis 20. The deployed configuration of distal section 24′ may be established by heat treating a shape memory material, using techniques that are per se known in the art, as described above. Distal section 24′ is configured to impose an increased radial outward force upon a patient's vessel and may further improve anchoring of the prosthesis within the vessel.

[0050] Distal end 38 of distal section 24′ further may comprise at least one barb 40 protruding from bend 32 and/or a distal portion of strut 31, as depicted in FIG. 4. Barb 40 is configured to extend radially outward and in a proximal direction with respect to a longitudinal axis of vascular prosthesis 20. Each barb 40 may comprise sharpened tip 41, which is configured to engage a patient's vessel when distal section 24′ is deployed in a vessel, as described in hereinbelow with respect to FIGS. 7.

[0051] Referring now to FIG. 5, different drug delivery modalities that may be used in conjunction with vascular prosthesis 20 of the present invention are described. In FIG. 5, illustrative turn 26′ of proximal section 22 comprises multiplicity of openings 28 disposed between solid regions 33, and further comprises at least one dimple 50 and/or through hole 52 disposed in solid

regions 33. Each dimple 50 and through hole 52 may have therapeutic agent 54 disposed therein. Therapeutic agent 54 may be disposed in the matrix of a bioabsorbable polymer, and the drug may be gradually released into a localized region of an arterial wall. Dimples 50 may be selectively disposed on an interior surface of turn 26', and/or disposed on an exterior surface of turn 26', as depicted in FIG. 5.

[0052] One or more turns 26 may be selectively coated with elastomeric polymer 56, such as polyurethane. Elastomeric polymer 56 may partially or fully cover selected regions of turns 26. For example, elastomeric polymer 56 may be disposed on one arc of the circumference of proximal section 22 to overlay an aneurysm and reduce blood flow into a sac of the aneurysm. Additionally, therapeutic agent 54 may be disposed on elastomeric polymer 56, which increases the working surface area of proximal section 22. Alternatively, the therapeutic agent may be disposed directly on solid region 33, either with or without the use of elastomeric polymer 56.

[0053] Referring now to FIG. 6, a delivery system suitable for use with the vascular prosthesis of the present invention is described. In FIG. 6, delivery system 60 is similar to that disclosed in U.S. Patent No. 4,665,918 to Garza et al., and includes catheter 61 having central lumen 62, nose cone 63 and outer sheath 64. Catheter 61 includes recessed portion 65 that cooperates with outer sheath 64 to retain proximal and distal sections 22 and 24 of vascular prosthesis 20 in their respective contracted states for transluminal delivery.

[0054] Delivery system 60 also may comprise fluid delivery lumen 67, which may be used to deliver chilled saline to vascular prosthesis 20 during delivery of the device. Fluid delivery lumen 67 may be disposed within catheter 61, as depicted in FIG. 6, and one or more ports 68 may be formed in a distal lateral surface of catheter 61 to facilitate fluid communication between lumen 67 and recessed portion 65.

[0055] Turning now to FIGS. 7, a preferred method of using vascular prosthesis 20 of the present invention, for example, in the treatment of an aneurysm, is described. It will be apparent from the method steps described herein that vascular prosthesis 20 also may be used in general stenting procedures, for example, to maintain patency in a vessel after a carotid angioplasty procedure, or may be used as an intravascular drug delivery device, or may be used in other applications apparent to those skilled in the art.

[0056] In FIG. 7A, vascular prosthesis 20 of FIG. 1 is provided in the fully contracted state disposed between recessed portion 65 of catheter 61 and outer sheath 64 of FIG. 6. Specifically, distal section 24 is compressed to its contracted delivery state about recessed portion 65 of catheter 61, and the plurality of turns of proximal section 22 are wound down to a contracted delivery state about recessed portion 65, as shown in FIG. 7A. Outer sheath 64 is disposed over proximal and distal sections 22 and 24, as depicted, to retain both sections in their contracted states.

[0057] First, guide wire 70 is percutaneously and transluminally advanced through a patient's vasculature, using techniques that are per se known in the art, until a distal end of guide wire 70 is positioned distal of

aneurysm **A**, which is situated in vessel **V**. Delivery system 60, having vascular prosthesis 20 contracted therein, then is advanced over guide wire 70 via central lumen 62 of catheter 61. Nose cone 63 serves as an atraumatic bumper during advancement of delivery system 60. Delivery system 60 is advanced under fluoroscopic guidance until proximal section 22 is situated adjacent aneurysm **A**, as shown in FIG. 7A.

[0058] During advancement of delivery system 60 though a patient's vasculature, chilled saline preferably is delivered to vascular prosthesis 20 via fluid delivery lumen 67 and port 68. The chilled saline may be used to increase the flexibility of prosthesis 20 to facilitate advancement of delivery system 60 over guide wire 70.

[0059] In a next step, outer sheath 64 is retracted proximally to cause distal section 24 to self-deploy distal of aneurysm **A**, as shown in FIG. 7B. Struts 31 of distal section 24 expand in a radial direction to engage an inner wall of vessel **V**. Barbs 40 of FIG. 3 may engage vessel **V**, and/or the distal end of distal section 24 may be biased radially outward with respect to the proximal end (see FIG. 3) to enhance the engagement between distal section 24 and the vessel wall.

[0060] With distal section 24 anchored distal of aneurysm **A**, outer sheath 64 then is further retracted proximally to cause distal turn 34 of proximal section 22 to unwind and deploy to its predetermined shape, as shown in FIG. 7C. As the outer sheath is further retracted, each subsequent turn 26 unwinds one at a time and engages and conforms to an inner wall of vessel **V** in a controlled manner. When prosthesis system 20 is fully deployed, delivery system 60 then is proximally retracted over

guide wire 70 and withdrawn from the patient's vessel, and guide wire 70 is removed.

[0061] In accordance with one aspect of the present invention, deploying distal section 24 prior to deploying proximal section 22 allows distal section 24 to serve as an anchoring mechanism that allows for a controlled deployment of the helical turns of proximal section 22. Advantageously, turns 26 of proximal section 22 will be accurately deployed within vessel **V**, with substantially no proximal or distal shifting with respect to the vessel as outer sheath 64 is retracted.

[0062] Moreover, by deploying distal section 24 prior to deploying proximal section 22, drawbacks associated with the device described in the above-referenced publication to Rivelli may be overcome. Specifically, without a distal anchoring element, the multiplicity of turns of the stent described in the Rivelli publication may experience a tendency to "bunch up," i.e., overlay one another, as the outer sheath is retracted due to friction between the turns and the outer sheath. In the present invention, distal section 24 serves as an anchoring mechanism prior to retraction of the outer sheath over the proximal section. Accordingly, such a distal anchoring mechanism overcomes potential friction and turns 26 will be less likely to bunch up.

[0063] In accordance with another aspect of the present invention, vascular prosthesis 20 of the present invention is configured to be flexible enough to substantially conform to the shape of vessel **V** without causing the vessel to remodel. In particular, the zig-zag configuration of distal section 24 and the helical configuration of proximal section 22 allow for increased flexibility of prosthesis 20. The pitch associated with

plurality of turns 26 may be varied to vary the overall flexibility of proximal section 22. A lower pitch, whereby adjacent turns 26 are spaced relatively close together, may be employed to increase flexibility of proximal section 22. A lower pitch is desirable, for example, to treat cerebral aneurysms so that turns 26 may conform to the vasculature without causing remodeling of the vessel. Conversely, a higher pitch, whereby adjacent turns 26 are spaced further apart, may be employed to increase the rigidity of proximal section 22. Such a design may be desirable for use in maintaining patency in a stenosed vessel by increasing rigidity of proximal section 22. As a yet further embodiment, the width of the coil may be tapered, as described in the Rivelli publication.

[0064] In accordance with another aspect of the present invention, covered sections 39 may be positioned to overlay aneurysm **A** to significantly reduce blood flow into aneurysm **A**. Alternatively, smaller rectangular openings 28 or small circular openings 29 may overlay aneurysm **A** to reduce blood flow into the sac of the aneurysm. Over time, the intima of vessel **V** will grow over plurality of turns 26 of proximal section 22 to completely exclude the aneurysm **A** from vessel **V**.

[0065] As noted hereinabove, the configuration of proximal section 22 depicted in FIG. 7C is merely for illustrative purposes. Any combination of covered sections 39, circular openings 29, large or small rectangular openings, or any other shape may be provided along turns 26, as desired. Plurality of turns 26 similarly may exclusively comprise one type of opening, e.g., small circular openings 29. Alternatively,

plurality of turns 26 may be completely solid such that the openings are omitted altogether.

[0066] In accordance with yet another aspect of the present invention, therapeutic agents may be delivered to expedite treatment of the aneurysm or prevent restenosis. As described hereinabove with respect to FIG. 5, therapeutic agent 54 may be delivered to a desired location within vessel **V**, either using internal or external dimples 50, through holes 52, elastomeric polymer 56 and/or solid regions 33 of one or more turns 26.

[0067] Therapeutic agent 54 may include, for example, antiplatelet drugs, anticoagulant drugs, agents used for purposes of providing gene therapy to a target region, or any other agent, and may be tailored for a particular application. Radiopaque markers (not shown) may be selectively disposed on turns 26 in the vicinity of the therapeutic agents to facilitate alignment of the therapeutic agents with a target site of a vessel wall. Advantageously, higher doses of such agents may be provided using vascular prosthesis 20 of the present invention, relative to previously known coils or stents having interconnected struts, due to the increased surface area associated with turns 26.

[0068] Referring now to FIGS. 8, an alternative embodiment of the vascular prosthesis of the present invention is described. Vascular prosthesis 120 comprises proximal section 122 and distal sections 124. Distal section 124 preferably is provided in accordance with distal section 24 of FIG. 1 and comprises a generally zig-zag configuration including struts 131 and bends 132.

[0069] Proximal section 122 includes a plurality of individual helical turns 126. Each turn has a distal end that is coupled to a respective bend 132 of distal section 124 at junctions 127, as shown in FIGS. 8. Individual helical turns 126 are aligned in a pattern such that each turn maintains its own helical curvature without overlapping with an adjacent turn, as depicted in FIG. 8. Individual helical turns 126 of vascular prosthesis 120 may be heat treated to self-deploy to the configuration shown, and may be wound down to a small diameter in which turns 126 are constrained within delivery system 60 of FIG. 6. The deployment of vascular prosthesis 120 is substantially similar to the deployment of prosthesis 20, as described in detail hereinabove with respect to FIGS. 7, and vascular prosthesis 120 encompasses many of the advantages noted hereinabove with respect to vascular prosthesis 20.

[0070] Referring to FIGS. 9A and 9B, vascular prosthesis 140 is described and includes torsional stabilizer 146 according to the principles present invention. Vascular prosthesis 140 comprises a proximal section 142, distal section 144 and torsional stabilizer 146. Proximal section 142, distal section 144 and torsional stabilizer 146 are joined at junction 148. Each of the proximal section, distal section and torsional stabilizer are capable of assuming contracted and deployed states, and each are depicted in their respective deployed states in FIGS. 9A and 9B.

[0071] In operation, distal section 144 is configured to be deployed within a vessel before torsional stabilizer 146, which is configured to be deployed before proximal section 142. Deploying distal section 144 first allows the distal section to serve as an anchor controls

subsequent deployment of the helical turns of proximal section 142. Torsional stabilizer 146 provides further contact with the vessel wall, thereby providing an additional anchor that transmits torsional forces proximally during deployment of proximal section 142. Distal section 144 and torsional stabilizer 146 preferably work in conjunction to balance the torsional force of the proximal section and thus stabilize the vascular prosthesis. This action is expected to further reduce shifting with respect to the vessel wall during deployment of proximal section 142. Advantageously, the above-identified order of deployment alleviates drawbacks associated with the prior art such as the tendency of the turns of the proximal section to "bunch up" during deployment.

[0072] The vascular prosthesis, including distal section 144, proximal section 142 and torsional stabilizer 146, preferably is formed from a solid tubular member comprising a shape memory material, such as Nitinol, processed as described above with respect to the embodiment of FIGS. 1. According to some embodiments, torsional stabilizer 146 includes at least one dimple or through-hole disposed on a solid portion of the torsional stabilizer.

[0073] Referring still to FIGS. 9, in the deployed state distal section 144 has a cell-like configuration comprising a pair zig-zags 144a, 144b joined by struts 144c. Alternatively, distal section 144 may include a single zig-zag configuration, such as described with respect to FIGS. 1. The cell configuration of FIGS. 9 is expected to be more rigid than the single zig-zag configuration, and hence is capable of applying, and withstanding, greater radial force. Either configuration

of distal section 144 may be formed by laser cutting a solid tube, as described hereinabove, to form the requisite pattern. Of course, as would be understood by those of ordinary skill in the art, distal section 144 may have many other configurations without departing from the scope of the present invention.

[0074] Proximal section 142 preferably comprises a helical ribbon including plurality of turns 152 having multiplicity of openings 154 provided in varying shapes and sizes. The multiplicity of openings are disposed between solid regions 150 of the shape memory material used to form vascular prosthesis 140. Proximal section 142 alternatively may comprise the helical mesh configuration of FIGS. 1 or any other suitable pattern. Proximal section 142 includes distal turn 156 that transitions into torsional stabilizer 146. Torsional stabilizer 146 comprises strut 158 that preferably remains substantially parallel to distal section 144.

[0075] Referring to FIGS. 9 and 10, distal section 144 is coupled to proximal section 142 at junction 148. More particularly, strut 144b extends in a proximal direction forming neck 149, which is attached to proximal section 142 at junction 148. It will be apparent to those skilled in the art that other strut arrangements may be employed to connect distal section 144 to proximal section 142. For example, more than one strut may be coupled between proximal section 142 and distal section 144. Alternatively, proximal section 142 and distal section 144 may be manufactured as two distinct sections, then coupled together.

[0076] In FIG. 10, the distal section and proximal section are mapped onto an X-Y coordinate system with junction 148 substantially defining an origin (X=0, Y=0).

The X-axis is substantially parallel to a longitudinal axis of vascular prosthesis 140 and the Y-axis is substantially orthogonal to the longitudinal axis of vascular prosthesis 140. Torsional stabilizer 146 generally comprises the portion of the proximal section that extends past the plane of the X-axis junction 148. According to one aspect of the present invention, torsional stabilizer 146 is an extension of proximal section 142 and may comprise a continuation of the helical pattern of the proximal section.

[0077] Torsional stabilizer 146 optionally may be biased outwardly to provide increased frictional contact with the vessel wall. Torsional stabilizer 146 also may comprise one or more radiopaque markers 160, such as a radiopaque marker band or coating. Radiopaque marker 160 facilitates positioning of torsional stabilizer 146 at a desired longitudinal position within a patient's vessel, and further facilitates alignment of vascular prosthesis 140 at a desired radial orientation within the vessel. For example, radiopaque marker 160 may be used to orient the prosthesis axially within the body vessel.

[0078] In FIG. 11, alternative vascular prosthesis 140' is shown having torsional stabilizer 162 in accordance with the principles of the present invention. Torsional stabilizer 162 comprises loop 164 of material that extends past the plane of the X-axis. Loop 164 is shaped substantially triangularly and includes first segment 164a disposed substantially parallel to the Y-axis, second segment 164b coupled to the proximal section, and third segment 164c. As would be appreciated by those of skill in the art, torsional stabilizer 162 may include other shapes and configurations without departing from the scope of the present invention. By

way of example, torsional stabilizer 162 may comprise two or more interconnected curvilinear loops.

[0079] In FIG. 12, further alternative vascular prosthesis 140" includes torsional stabilizer 168. Torsional stabilizer 168 comprises loop 170 of material that extends past the plane of both the X-axis and Y-axes, and illustratively includes semicircular portion 170a. Of course, as would be appreciated by those of skill in the art, torsional stabilizer 168 may include other shapes and configurations without departing from the scope of the present invention.

[0080] While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.